AD's Process for DfE Requests

PPDC Workgroup on Comparative Safety Statements for Pesticide Product Labeling

Meeting

Tuesday, October 13, 2009

Revised 10/13/09

Background

- OPP and OPPT's DfE staff are working together to determine feasibility of allowing products that have passed the DfE review to submit a label amendment to OPP in order to place the logo on pesticide products.
- OPP and OPPT's DfE staff envisioned that this would be a two-part review process
  - Products would have to complete the DfE review.
  - Products would then have to complete the OPP review.

OPP Factors to Consider

- No acute toxicity I or II products – Danger or Warning signal word
- No known, likely, or suggestive carcinogens
- No known developmental, reproductive, mutagenic, or neurotoxicity issues
- No outstanding “conditional registration” data issues for the active ingredient
- No PPE required to use the product

OPP/AD DfE Submission Requests

- AD DfE submissions will receive a PRIA code of A570.
- The fee associated with this type of submission is $3,308.
- There is a 120 day timeframe for completion.

AD 21 Day Completeness Review

- Cover Letter
- Certification Statement
- DfE Acceptance Letter
- CSFs – DfE accepted formulations

  - basic and all alternate formulations
- Proposed Label
- Data Matrix (if citing another product's acute tox. data)

Review Process

Create DfE Review Science Team.

Checklist utilized by the AD DfE Review Science Team will be developed and posted on the AD website.

Science Team has 90 days to assess the submission.

Upon completion of the review, the submission is sent to the Product Manager.

DfE Review Science Team Members

- 2 Toxicologists
- 1 Eco/Fate Assessor
- 1 Product Specific Toxicologist
- 1 Microbiologist
- 1 Chemist
- 1 AD Project Coordinator

DfE Review Science Team Duties

- Active Ingredient Assessment – A review of the human health risk assessment to validate active meets OPP requirements

- Product Formulation Assessment – A review of the acute toxicology profile to validate the formulation meets OPP requirements

DfE Review Science Team Duties (cont'd)

- Confirmation of product chemistry
- Confirmation of no unresolved 6(a)(2) issues
- Confirmation of no unresolved efficacy failures (ATP related or otherwise)
- Confirmation of no unresolved enforcement actions.

Acceptable Regulatory Decision

- Stamp Label approving DfE logo
- Label may add the OPP DfE website address

Unacceptable Regulatory Decision

- As a condition of the Pilot, an unacceptable regulatory decision would result in one of the following:
  - Company agrees to withdraw the submission.
  - Company may request a 45 day negotiation of the due date.
  - The Agency may issue a “Not Grant” determination.

Timeline for DfE Pilot

- Originally, OPP envisioned the DfE Pilot would be conducted for an 18 month cycle.
- The subgroup requested additional time to accommodate the State registration process.
- OPP will allow submissions under the pilot beginning May 2010.
- OPP envisions the end of the pilot May 2013

Next Steps

- Finalize Certification Statement
- Placement and Prominence of Logo
- Internal “Test Run” of AD DfE Process